

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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IN RE:	:	No. 1:06-md-1789
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FOSAMAX PRODUCTS LIABILITY	:	
LITIGATION	:	JUDGE KEENAN
	:	
<i>This Document Relates to:</i>	:	MAGISTRATE JUDGE FRANCIS
	:	
Maley v. Merck & Co., Inc.,	:	
Case No. 01:06-CV-04110	X	

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**PLAINTIFF LOUISE H. MALEY'S OPPOSITION TO
DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

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Plaintiff Louise H. Maley ("Plaintiff") respectfully submits this memorandum in opposition to defendant Merck & Co., Inc.'s ("Defendant" or "Merck") motion for summary judgment.

PRELIMINARY STATEMENT

Plaintiff filed this product liability action because she developed osteonecrosis of the jaw. Plaintiff asserted basic common law tort claims, including product liability, negligence and failure to warn claims. Defendant moved for summary judgment on all claims.

For the reasons stated below, Defendant's motion for summary judgment as to Plaintiff's claim for negligent failure to warn should be denied. Plaintiff does not intend to pursue the other claims originally asserted in her complaint.

MATERIAL FACTS

Plaintiff Louise Maley is a resident and citizen of Indiana, and has been for many years. Plaintiff was prescribed Fosamax for prevention of osteoporosis beginning in 1996 or 1997, and continued to take Fosamax until March 2006. In April 2004, Plaintiff began experiencing pain in her back upper right jaw. She sought treatment from various medical and dental professionals. The pain, which has been severe at times, has been treated with surgeries and medication, but always recurs. In approximately May 2006, the pain spread to her bottom jaw. Plaintiff's medication has been increased multiple times, to try to alleviate her pain. The evidence in this case shows that Plaintiff has osteonecrosis of the jaw as a result of the Fosamax. ONJ is a serious and often painful and debilitating jaw condition.

ARGUMENT

I. LEGAL STANDARD

Defendant has moved for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. Pursuant to Rule 56(c), summary judgment "should be rendered if the pleadings, the discovery and the disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c).

When deciding a motion for summary judgment, a district court "must construe the evidence in the light most favorable to the nonmoving party, drawing all inferences in that party's favor. *Jeffreys v. New York*, 426 F.3d 549, 553 (2d Cir. 2005) (citation omitted); *see also, Hayes v. New York Dep't of Corr.*, 84 F.3d 614, 619 (2d Cir. 1996). "If, as to the issue on which summary judgment is sought, there is any evidence in the record from which a reasonable inference could be drawn in favor of the opposing party, summary judgment is improper." *Hetchkop v. Woodlawn at Grassmere, Inc.*, 116 F.3d 28, 33 (2d Cir. 1997) (citations omitted).

At the summary judgment stage, the judge "must ask himself not whether he thinks the evidence unmistakably favors one side or the other but whether a fair-minded jury could return a verdict for the plaintiff on the evidence presented." *Anderson v. Liberty lobby, Inc.*, 477 U.S. 242, 252 (1986). "Credibility assessments, choices between conflicting versions of the events, and weighing of the evidence are matters for the jury, not for the court on a motion for summary judgment." *Hetchkop*, 116 F.3d at 33 (2d Cir. 1997) (citations omitted); *see also, Anderson*, 477 U.S. at 249 (1986), *Jeffreys*, 426 F.3d at 553-54 (2d Cir. 2005), *Hayes*, 84 F.3d at 619 (2d Cir. 1996).

In the present case, there is sufficient evidence for a jury to find for Plaintiff. A reasonable jury could find that Plaintiff developed ONJ due to her long term use of Fosamax and that Defendant's warning was defective. That Defendant does not find that evidence credible, which is the essential basis for its motion, is not determinative. Accordingly, Defendant's motion for summary judgment should be denied.

II. CAUSATION

Defendant moves for summary judgment on the grounds, in part, that Plaintiff cannot prove either general or specific causation. Plaintiff, however, has produced more than sufficient admissible evidence, in the form of expert reports, on both general and specific causation to rebut defendant's motion. Plaintiff's expert reports at the very least raise genuine issues of material fact as to the cause of Plaintiff's jaw problems.

A. General Causation

Plaintiff will rely on several experts, including those designated and proffered by the Plaintiffs' Steering Committee in the related multi-district litigation. Several of Plaintiff's experts have stated, in their expert reports and deposition testimony, that Fosamax causes ONJ. Those experts include, among others: Alastair N. Goss, DDSc, FRACDS (OMS), FICD; Dr. Robert E. Marx, D.D.S.; John William Hellstein, DDS, MS; and, Mahyar Etminan, PharmD, Msc (Epidemiology).

Dr. Goss is a Professor of Oral and Maxillofacial Surgery at the University of Adelaide, South Australia, the Director of Oral and Maxillofacial Surgery at The Royal Adelaide Hospital, and the Director of Oral and Maxillofacial Surgery at The Adelaide Dental Hospital. (Miller Decl. Ex. D.) He also maintains a Private Specialist Practice on Adelaide, Australia. (*Id.*) Dr. Goss opined

that "there is a causative association between the bisphosphonate class of drugs, including Alendronate [Fosamax], and osteonecrosis of the jaws (ONJ). This opinion is based on careful review of the international scientific literature and independent research investigations which I have conducted in Australia." (*Id.*)

Dr. Robert Marx is a Professor of Surgery and Chief of the Division of Oral and Maxillofacial Surgery at the University of Miami Miller School of Medicine. (Miller Decl. Ex. E.) He also has a very active oral and maxillofacial clinical practice at the University of Miami. (*Id.*) Dr. Marx has stated that bisphosphonates, including Fosamax, cause ONJ. (*Id.*)

Dr. Hellstein is a clinical professor at the University of Iowa, College of Dentistry and has a joint appointment in the department of Hospital Dentistry at the University of Iowa Hospitals and Clinics. (Miller Decl. Ex. G.) Dr. Hellstein is the laboratory director for the surgical oral pathology laboratory at the College of Dentistry. (*Id.*) He also sees patients in the clinic. (*Id.*) Dr. Hellstein has stated, among other things, that bisphosphonate induced ONJ "occurs only in the presence of bisphosphonates and nitrogen containing bisphosphonates, such as Fosamax are particularly able to cause" ONJ. (*Id.*)

Mayhar Etminan, PharmD, MSc (Epidemiology), is a pharmacoepidemiologist. (Miller Decl. Ex. H.) Dr. Etminan is an Assistant Professor of Medicine at the University of British Columbia and a research scientist at the Center for Clinical Epidemiology and Evaluation in Vancouver. (*Id.*) One of his main areas of research is identifying rare adverse drug events using large administrative databases. (*Id.*) Dr. Etminan has stated that a "review of the empirical data on the topic of bisphosphonate-related ONJ and the subset for Fosamax-induced ONJ shows that there

is reliable data establishing that bisphosphonates and, particularly, Fosamax cause osteonecrosis of the jaws in the general population.

Defendant's argument that that Plaintiff cannot prove general causation fails because it is based on a mis-characterization of Plaintiff's claim in this case and flawed diagnosis by one of Plaintiff's treating dentists. According to Defendant, Plaintiff cannot prove general causation because she has proffered no evidence that Fosamax can cause neuralgia inducing cavitation osteonecrosis ("NICO"). Plaintiff does not claim that she has, or had, NICO. Plaintiff's claims in this case are premised on the allegations, and evidence, that she has ONJ. Moreover, NICO is not a generally accepted medical or dental disease.

The evidence supports Plaintiff's claim that she had ONJ and that it was caused by Defendant's drug Fosamax. Plaintiff's expert Rand Redfern, D.D.S., after reviewing Plaintiff's relevant medical records, including various x-rays and MRIs, concluded that "Ms. Maley developed BRONJ (Bisphosphonate Related Osteonecrosis of the Jaw) while using a specific bisphosphonate - Fosamax." (Miller Decl. Ex. A.) Dr. Redfern gave his opinion "to a reasonable degree of medical probability and certainty." (*Id.*)

Plaintiff does not, and never has, claimed to have NICO. In fact NICO is not generally accepted as a specific condition or disease. According to Dr. Marx, "[t]he vast majority of dental professionals, including the majority of Oral and Maxillofacial Surgeons, do not accept NICO as a pathological condition or as a diagnosis." (Miller Decl. Ex. F, ¶ 13.) Dr. Marx also noted that "no oral pathology text books other than the one edited by the proponents of NICO recognize NICO for inclusion in their text and no association or society of medicine or dentistry recognize NICO as a real disease." (*Id.*)

Because Plaintiff has proffered more than enough evidence to raise triable issues of fact with regard to general causation, Defendant's motion for summary judgment should be denied.

B. Specific Causation

Plaintiff has designated Dr. Rand Redfern as an expert in this case. Dr. Redfern has prepared an expert affidavit and been deposed. (Miller Decl. Ex.s A and B.) Dr. Redfern is a dentist specializing in oral facial pain and maxillofacial radiology. (Miller Decl. Ex. A.) He has been a dentist for thirty six years and has been in private practice since 1979 and continues to see patients for consultation and treatment. (*Id.*) Dr. Redfern has completed a number of radiology fellowships, including one or more related to oral and maxillofacial pain. (*Id.*) He is a member of numerous professional societies. (*Id.*) Dr. Redfern has made various invited presentations and presented a number of papers. (*Id.*) Recently, he has made several presentations related to bisphosphonate induced ONJ. (*Id.*) Dr. Redfern has more than kept abreast of the published literature relating to bisphosphonate induced ONJ, reading articles from numerous authors in many journals. (Miller Decl. Ex. B, pp. 18-29.) Dr. Redfern has seen patients he determined had bisphosphonate related ONJ and has reported his clinical experience to the FDA. (*Id.*, pp. 72-74, 93.)

Dr. Redfern has opined, to a reasonable degree of medical probability and certainty, that Plaintiff developed ONJ as a result of using Fosamax. ((Miller Decl. Ex. A.) Dr. Redfern testified that he based his opinion on Plaintiff's clinical history. (Miller Decl. Ex. B, 97-101.) Dr. Redfern reviewed the relevant medical records in this case. (Miller Decl. Ex. A.) He also reviewed various x-rays and scans, including at least one he requested. (Miller Decl. Ex. A.)

Defendant argues that Dr. Redfern's proffered testimony is not admissible under Rule 702 of the Federal Rules of Civil Procedure. According to Defendant Dr. Redfern's testimony is not

based on specialized knowledge, is not scientifically reliable, and does not fit the facts of this case. Defendant is wrong on each count.

Dr. Redfern is qualified to be an expert in this case and to testify about bisphosphonate related ONJ. As noted above, Dr. Redfern is a practicing dentist specializing in oral facial pain and maxillofacial radiology. He has been practicing for more than thirty years. Moreover, he has experience with patients who have bisphosphonate related ONJ. Ultimately, Defendant objects to Dr. Redfern because he is not an expert on NICO. Plaintiff does not claim that she had NICO and any diagnosis to the contrary is mistaken.

Dr. Redfern's conclusions are based on Plaintiff's clinical history and the medical records he reviewed. Defendant asserts that Dr. Redfern's opinions are not reliable because he "conceded . . . that Plaintiff never met the criteria for BRONJ." All Dr. Redfern conceded was that Plaintiff did not meet the definition set out by one professional society. He did not concede that she did not have bisphosphonate related ONJ; to the contrary, he stated in his report and testified that in his opinion she did have ONJ and that it was related to her use of Fosamax.

Finally, Defendant argues that Dr. Redfern's testimony does not fit the facts of this case because Plaintiff had NICO. Plaintiff did not have NICO.

Because Plaintiff has proffered sufficient evidence to raise a triable issue of fact as to whether she had bisphosphonate related ONJ caused by Fosamax, Defendant's summary judgment motion should be denied.

III. **FAILURE TO WARN CLAIM**

Defendant argues that Plaintiff's failure to warn claim, under Indiana law, fails because Plaintiff has no evidence to show that a different warning would have changed her prescribing

physician's decision to prescribe Fosamax. According to defendant, in order to proceed on her failure to warn claim, Plaintiff must prove that an adequate warning would have convinced the treating physician to change his or her course of treatment, thereby avoiding developing ONJ. Defendant, however, mis-states or mis-characterizes the law.

Indiana Courts apply the Learned Intermediary Doctrine. *See Minisan v. Danek Med., Inc.*, 79 F.Supp.2d 970, 978 (N.D. Ind. 1999). Under the Learned Intermediary Doctrine, manufacturers of prescription medical products duty to warn runs only to physicians. *Id.* The manufacturers are not required to warn patients directly. *Id.* Moreover:

when adequate information is provided to the physician, the manufacturer will not be held liable despite the physician's failure to give notice to the patient.

Talley v. Danek Med., Inc., 7 F.Supp.2d 725, 730 (E.D. Va. 1998) (emphasis added). Manufacturers may also get the benefit of the Learned Intermediary Doctrine, and avoid liability, if the prescribing physician independently knows of the risks of the medication despite the manufacturer providing inadequate information. *Id.* In other words, a pharmaceutical manufacturer, like Defendant here, must provide adequate warnings or hope that the prescribing physician somehow learns of the risks associated with the manufacturer's products some other way. The issue of the adequacy of a warning is a question of fact for the jury.

In this case, the evidence shows that Defendant never provided an adequate warning. Plaintiff has proffered opinions about Defendant's warning related to Fosamax from two experts, Suzanne Parisian, M.D. and Curt Daniel Furberg, M.D., Ph.D. (Miller Decl. Ex. I and J.) Dr. Parisian opined, among other things, that Defendant's Fosamax warning was inadequate because: Merck adequately disclose information to the FDA; Merck failed to its labeling, instructions and

warnings; and, Merck failed to timely inform physicians and health care providers about the association between Fosamax and ONJ. (Miller Decl. Ex. I, pp. 8-10.) Likewise, Dr. Furberg has stated that Merck refused to broadly inform physicians about the risk of Fosamax-induced ONJ and that Merck engaged in a series of misrepresentations, suppressions and delays in disseminating data that masked the harmful effects of Fosamax. (Miller Decl. Ex. J, pp.8, 32.)

Moreover, as Defendant points out, the prescribing physician, Dr. Lawton, relied on the Physician's Desk Reference for information about drugs. This information was prepared by Defendant. There is no evidence in this case, certainly none identified by Defendant, to show that Dr. Lawton had any idea about the actual risks of a patient developing ONJ from Fosamax.

Because the evidence shows that Defendant never provided an adequate warning, Plaintiff's failure to warn claim should proceed and Defendant's motion for summary judgment should be denied.

CONCLUSION

Based on the foregoing this Court should deny Merck's motion for summary judgment

Dated: June 8, 2009

Respectfully Submitted,

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CERTIFICATE OF SERVICE

On this 8th day of June, 2009, I certify that I served all counsel of record, including counsel for defendant identified below, by filing the foregoing **PLAINTIFF LOUISE H. MALEY'S OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT** by using this Court's ECF system:

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